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SENSITIVE
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STATE FOR EEB/TPP/MTAA/ABT ARYAN
STATE FOR C MLOWDEN
STATE FOR J BOBO
STATE PASS USDA/ERS
STATE PASS USDA/FAS/OSTA BERMAN/PORTER/JONES
STATE PASS USDA/FAS/OCRA CHINA DESK
STATE PASS USDA/OGA
STATE PASS USDA/APHIS/SIMMONS/HERON
STATE PASS USTR FOR STRATFORD
STATE PASS USTR CLARKSON
STATE PASS FDA/DEITZ
STATE PASS EPA/WOZNIAK

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SUBJECT: 6th U.S.-China Technical Working Group Meeting in Beijing

(U) This cable is Sensitive But Unclassified. Please protect accordingly.

¶1. (SBU) On September 15, officials and technical experts from the United States and China convened the Sixth Meeting of the U.S.-China Biotechnology Technical Working Group on Food and Environmental Safety (TWG). Discussion focused on scientific and regulatory issues relevant to genetically engineered plants and the foods derived from them. Included in this discussion was an explanation of both the U.S. and Chinese approaches to the low level occurrence in commerce of unauthorized genetically engineered (GE) plants and material derived from such plants. The discussions were very informative and open, with the Chinese delegation presenting detailed information about their development of Bt rice. The formal TWG meeting was preceded by a field trip to Shanghai to discuss the development of transgenic goats, environmental safety assessment of biotech products, and database and detection methods for biotech products. END SUMMARY.

BIOTECH RELATIONSHIP MOVES FORWARD

¶2. (SBU) Prior to the TWG, the MOA hosted a field trip to Shanghai to continue the recent TWG tradition of "hands-on" visits with experts to discuss technical issues related to agricultural biotechnology. Accompanied by Mr. Fu Zhongwen, Project Officer with the Shanghai Center for Science and Technology Development, APHIS-Biotechnology Regulatory Services met with key province officials from the Science and Technology Department and Division of Foreign Affairs of the Shanghai Municipal Agricultural Commission. Meetings with private sector researchers, including the Chairman of the Board and President, Cheng Guoxiang, of Shanghai Genon Bio-Engineering Company provided significant new information about Chinese researchers' achievements related to transgenic animals. This relatively new company, founded in 1999, has developed transgenic goats, which express human lactoferrin and lysozyme intended for use in nutritionally-enhanced foods. Additionally, Genon is undertaking research focused on improving animal health, particularly gene expression related to scrapies. Discussions at Fudan University with Professor Lu Bao-Rong, a key National Biosafety Committee (NBC) member and other academics focused on rice gene flow research used to support China's environmental safety

assessment of GE rice. Professor Lu provided numerous peer-reviewed research studies which have been shared with MOA regulators. USDA also met with Professor Zhang Dabing, another NBC member, at Shanghai Jiao Tong University to discuss database and detection methods for biotech products and reference material preparation. Much of Professor Zhang's research efforts are aimed at providing resources to assist in the enforcement of China's labeling policy and to harmonize and standardize testing methodologies. Professor Zhang is actively engaged in various on-going international cooperation activities on detection methodologies. Shanghai Jiao Tong University will also be the future home of a special center for consumer education on biotechnology.

13. (SBU) The United States and China convened the 6th Meeting of the U.S.-China Biotechnology Technical Working Group (TWG) in Beijing, September 15, 2009, hosted by the Chinese Ministry of Agriculture. Beverly Simmons, Associate Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service led the U.S. delegation, which included representatives from USDA's Foreign Agricultural Service (FAS), the USDA's Animal Health and Plant Inspection Service (APHIS), the USDA's Agricultural Research Service (ARS), the Food and Drug Administration (FDA)'s Center for Food Safety and Applied Nutrition (CFSAN) and Office of International and Special Programs/Office of the Commissioner (OC), and the Environmental Protection Agency (EPA) Office of Pesticides, Biopesticides and Pollution Prevention Division (OPP/BPPD). Duan Wude, Director General, Center for Science and Technology Development, Ministry of Agriculture (MOA), led the Chinese delegation, which included representatives from the Ministry of Agriculture, the Chinese Academy of Agricultural Sciences (CAAS), the China Agricultural University, the Chinese Academy of Inspection and Quarantine Sciences, and the Ministry of Health's (MOH) Center

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for Disease Control (CDC).,

14. (SBU) In the lead up to the TWG, both U.S. and Chinese regulators outlined three meeting objectives which included: 1) enhance the scientific basis of safety regulation and mitigate risks, 2) improve the understanding of the policies and practices of the relevant regulatory agencies in the United States and China, and 3) identify ways to communicate relevant information that can help regulators to better address low level presence (LLP). Following the agreed schedule, the meeting focused on: 1) technical support to safety regulation in the wake of the rapid development of modern biotechnology and the biotech industry, and 2) approaches used in the United States and China where there is LLP of GE plants that have not yet completed all of the relevant regulatory reviews.

15. (SBU) FDA, EPA, and APHIS representatives provided an update on recently completed U.S. evaluations and products under review. China responded with questions about how the regulatory agencies evaluate and regulate products, the length of the review process, and USG interaction with developers and the public. After further U.S. explanation, China complimented the U.S. on its early interaction with researchers and the transparency of its regulatory system, including the information provided on its web site. China noted its interest in receiving more specific information on VIP proteins as used in insect resistant cotton and maize, particularly EPA's Science Advisory Panel reports. EPA offered to supply this additional information.

16. (SBU) Professor Wu Kongming, Chairman of the National Biosafety Committee, from the Chinese Academy of Agricultural Sciences provided a detailed presentation on the environmental monitoring of Bt cotton after commercialization in China. China noted that Bt cotton continues to control Cotton and Pink Bollworm, although predators, and specifically mirids, have increased significantly as chemical applications in Bt cotton fields have decreased. These findings have implications for China's evaluation of other BT crops, especially corn, since cross resistance concerns will need to be addressed.

17. (SBU) EPA provided a summary of the requirements for environmental monitoring for plant-incorporated protectants and food safety evaluation for those products entering the food and feed

supply, including how the requirements have changed over time. The use of refuges to address insect resistance was also raised.

¶8. (SBU) The United States invited China to ask questions about the U.S. risk assessment process. China expressed interest in receiving more detailed information on how risks are assessed for new products with insect resistance traits, altered nutritional quality, and drought tolerance. The United States suggested these could be topics for future technical discussions. China also asked if there were any new considerations on labeling in the United States. In reply, FDA described the U.S. approach to the labeling of foods produced through biotechnology. China responded by noting its own labeling situation as complex, and opined whether traits that improve crop quality, such as high oleic acid soybeans raise questions about the principle of substantial equivalence.

¶9. (SBU) Considerable time was devoted to discussing low level presence (LLP) policies in China and the United States, including their application, interagency coordination, and communication to the public. FDA provided an overview of the U.S. policy and its application. U.S. regulatory officials discussed why, when, and how regulatory violations would be determined under U.S. LLP policies as well as when mitigation would be needed. FDA and EPA emphasized the serious regulatory consequences if food has pesticidal substances or residues that exceed allowable levels (tolerances) or if an exemption from tolerance has not been established. Both sides discussed some ideas about ways to avoid such occurrences, and there was general agreement that this could be a useful area for further discussion before the next TWG. Regulatory officials also presented case studies on LL601 rice and Bt10 maize to illustrate how U.S. regulatory agencies have responded to LLP incidents and lessons learned. Questions were raised regarding the presence of LL601 rice

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on the U.S. market and why it was never commercialized, as well as planting and export plans for LL62 rice.

¶10. (SBU) Professor Jia Shirong (Biotechnology Research Institute, CAAS) presented a detailed case study on the development, characteristics, and effectiveness of Chinese Bt63 rice. China noted that low levels of Bt63 rice were found in Hubei Province in ¶2005. In response, the government of Hubei Province conducted inspections of the rice producing counties in order to control the original seed source and to prevent illegal seed production. Illegal Bt63 rice seedlings were destroyed. Follow up action also included sampling rice seed on the market, conducting Bt gene testing before planting for ensuing years, and surveying, inspecting, and testing breeding materials. When asked when China would engage other regulatory authorities around the world on Bt63 rice, Chinese officials hesitated before stating that they already had approached the EU and that both countries considered Bt63 rice to be a safe product. During further discussion, they could not say when Bt63 rice might be approved for commercialization in China and when or if they would seek import approval from third country regulators. This was the most detailed discussion that the Chinese representatives have had with US officials on Bt-rice, and the U.S. delegates were encouraged that this exchange might lead to additional exchange of technical information that would be relevant to regulatory reviews in each country.

¶11. (SBU) MOA presented China's developing policy on LLP. MOA stated that China is: observing international discussions on LLP, as well as conducting its own scientific research; continuing to work with its trading partners on LLP, including the United States and the EU; and trying to find a solution that fits its situation. MOA reminded the U.S. delegation that China maintains a zero tolerance for unapproved events because there is no legal provision in Chinese law for LLP. That said, Chinese officials recognize that the United States attaches great importance to this issue, as does industry, and acknowledged that it would be very difficult to completely ban products based on a zero tolerance. They said that China's goal is to develop a science-based LLP policy that is feasible to implement in a way that will control risks. The relationship between LLP and China's compulsory labeling requirement indicated that changes to China's labeling policy may be necessary. Noting China's lack of a legal framework for LLP, Chinese officials repeatedly suggested that

they hope the USG can strengthen its management of research institutions and trading companies so as to reduce the occurrence of LLP.

NEXT STEPS

¶12. (SBU) Director General Duan Wude expressed satisfaction with the meeting and commented that the discussion was more diverse, detailed, and comprehensive than in the past. He believes both sides now have a better understanding of each other's position on the issues. He expects the discussions at future TWG meetings will become broader and deeper. For future TWG meetings, he would like to discuss the product review process - such as the petition process-at a more in-depth level.

¶13. (SBU) ADA Simmons expressed continued USG support for the TWG. Simmons suggested that we find ways to more easily share information of interest because we have so many common interests. She noted that as global leaders on biotechnology, both countries should strive to advance our common interests in international fora.

¶14. (SBU) Priority areas of follow-up could include the development of guidance for Chinese developers on how to navigate the U.S. regulatory system. Similarly, additional attention should be given to reengaging the Chinese in the area of risk communication, and building on previous work in this area.

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